

Notice of Allowability

Application No.

09/460,605

Examiner

Gollamudi S Kishore, PhD

Applicant(s)

DISCHER ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1-24-04 and 3-22-04.
2. ☒ The allowed claim(s) is/are 30-43.
3. ☒ The drawings filed on 14 December 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**


7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. <u>1-24-04</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |


Gollamudi S Kishore, PhD
Primary Examiner
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Evelyn McConathy on 3-22-04.

The application has been amended as follows:

- 1) Claims 1-29 have been Cancelled.
- 2) The following claims have been added.

30. A polymersome vesicle consisting essentially of a semi-permeable, thin-walled encapsulating membrane and at least one encapsulant encapsulated therein, wherein the membrane is formed in an aqueous solution without the use of organic solvent, wherein the membrane comprises one or more wholly synthetic, super-amphiphilic molecules that are polymeric, having a number average molecular weight >1400, wherein at least one super-amphiphile molecule is a block copolymer, and wherein the polymeric molecules directly self assemble into vesicles due to amphiphilicity and without need for post-assembly polymerization or crosslinking.

31. The polymersome vesicle of claim 30, wherein the super-amphiphilic molecules comprising the membrane are all block copolymers.

32. The polymersome vesicle of claim 30, wherein the super-amphiphilic molecules of the membrane comprise at least one multi-block copolymer.

33. The polymersome vesicle of claim 30, wherein the super-amphiphilic molecules of the membrane comprise at least one diblock copolymer.

34. The polymersome vesicle of claim 30, wherein the super-amphiphilic molecules of the membrane comprise at least one triblock copolymer.

35. The polymersome vesicle of claim 30, wherein the at least one polymer of the block copolymer is selected from the group of polymers consisting of polyethylene oxide (PEO), poly(ethylene) (PEE), poly(butadiene) (PB), poly(styrene) (PS) and poly(isoprene) (PI).

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36. The polymersome vesicle of claim 30, wherein the at least one encapsulant is selected from the group consisting of therapeutic compound, dye, indicator, biocide, nutrient, protein or protein fragment, salt, gene or gene fragment, steroid, and gas.

37. The polymersome vesicle of claim 30, wherein the polymersome and said encapsulant are biocompatible.

38. A method of preparing the polymersome of claim 30, comprising preparing the polymersome by film rehydration, bulk rehydration, or an electroformation, or any combination thereof, and subsequent to, or simultaneously with polymersome preparation, encapsulating at least one encapsulant in the polymersome, thereby loading the polymersome vesicle.

39. A method of releasing at least one encapsulant from the polymersome vesicle of claim 30 to an environment immediately surrounding the polymersome, wherein the method comprises delivering the polymersome and said encapsulant contained therein to an intended environment, and modifying the polymersome membrane or the environment to effect the release of said encapsulant.

40. The method of claim 39, wherein said method of release further comprises administering the polymersome to a patient, and releasing said encapsulant from the polymersome to said patient, wherein the polymersome and encapsulant are biocompatible.

41. The method of claim 40, wherein said encapsulant released to the patient from the polymersome is selected from the group consisting of therapeutic compound, dye, indicator, biocide, nutrient, protein or protein fragment, salt, gene or gene fragment, steroid, and gas.

42. A method of controlling release of the encapsulant from the polymersome of claim 30 by modulating the composition of the polymersome.

43. A method of controlling release of the encapsulant from the polymersome of claim 42 by destabilizing the polymersome by exposing the destabilized polymersome membrane to one or more chemicals or to propagated light, X-ray or UV waves, IR irradiation, sound, ultrasound, heat, or motion.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK